

REMARKS

The pending Office Action addresses and rejects claims 1-27.

Amendments to the Claims

Claim 18 is amended to include the limitations of claim 26, which is now cancelled. No new matter is added.

Panel Decision

At the outset, Applicant notes that in the July 19, 2007 Notice of Panel Decision from Pre-Appeal Brief Review, the panel agreed to withdraw the pending rejections and issue a new Office Action. However, in the new Office Action mailed October 4, 2007 the Examiner issues the same rejection that was withdrawn by the panel. Accordingly, while Applicant provides the following additional remarks in response to the pending rejections, Applicant believes that the rejections were already overcome. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection Pursuant to 35 U.S.C. §103

Claims 1-11, 13, and 15-27

The Examiner continues to reject claims 1-11, 13, and 15-27 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,291,896 to Fonger et al. ("Fonger") in view of U.S. Publication 2003/0097082 to Purdy et al. ("Purdy"). The Examiner argues that Fonger teaches the claimed invention except for "(a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna." The Examiner relies on Purdy to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Purdy to arrive at the claimed invention.

Independent claim 1 recites an implantable fluid management device having an elongate catheter, a sensor embedded in a distal portion of the catheter, and at least one wire having a distal end coupled to the sensor and a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor. Independent claim 18 recites an implantable fluid management device having an elongate catheter, a sensor disposed within a wall of a distal portion of the catheter such that the sensor is adapted to sense conditions present around the catheter, at least

one wire extending through the catheter, and a slit extending through an outer wall of the catheter. The at least one wire has a distal end that is coupled to a sensor and a proximal end that is mated to an external antenna.

It would not have been obvious to modify the device of Fonger to include a distally disposed pressure sensor embedded or disposed in a wall in a distal portion of the catheter. The Examiner asserts that:

The claims would have been obvious because *the substitution of one known element for another would have yield predictable results* to one of ordinary skill in the art at the time of the invention. Because both Fonger et al and Purdy et al teach pressure measurement catheters, it would have been obvious to one skilled in the art at the time of the invention to substitute one distally disposed pressure sensor configuration for the other to achieve the predictable results of measuring a pressure of fluid surrounding the distal portion of catheter via a distally disposed pressure sensor configuration in a pressure measurement catheter system.

(Office Action dated October 4, 2007, pg. 4; Emphasis added). Pursuant to the "Examination Guidelines for Determining Obviousness Under 35 U.S.C 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" (hereinafter "the Guidelines"), the Examiner appears to be relying on the rationale set forth in Section III(A)) of the Guidelines.

In order to reject a claim based on the rationale under Section III(A), the Examiner must articulate, among other requirements,:

a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that *in combination, each element merely would have performed the same function as it did separately.*

(Emphasis added). Combining Fonger with Purdy does not yield a combination where each element performs the same function as it did separately. In fact, the pressure sensor of Fonger would function markedly different in combination with Purdy than it does separately. The basic principle of Fonger is to provide a sensor that is *released* from a catheter to enable the sensor to be *implanted* in an *exterior surface* of a vessel to externally detect the pressure within the vessel through the vessel wall. Modifying Fonger in view of Purdy to embed or dispose the sensor in a distal portion of the catheter would change the function performed by the sensor. Specifically, Fonger's pressure sensor could no longer be *released* from the catheter to allow the sensor to be *implanted* in an *exterior surface* of a

vessel, as the combination would yield a pressure sensor that is fixed on a distal portion of a catheter and unable to implant in any surface. Moreover, the Fonger device is designed to externally measure the pressure in the heart through the vessel wall. Modifying Fonger to include an embedded sensor would frustrate this purpose, as the modified catheter would have to be inserted into a vessel and could not be implanted on an external surface of the vessel. Thus, embedding or disposing the sensor of Fonger in the catheter, as required by independent claims 1 and 18, is not merely a simple substitution of known elements as the combination does *not* yield a device that performs the same function as it did separately. Rather, the combined device is much more invasive and functions markedly different than the device contemplated by Fonger.

Accordingly, independent claims 1 and 18, as well as claims 2-17 and 19-25 and 27 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Applicant further notes that independent claim 18 additionally requires an antenna coupled a proximal end of a wire extending through the catheter. One having ordinary skill in the art would not be motivated to modify the device of Fonger to include an antenna as taught by Purdy. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). There is no advantage to modifying the cardiac output probe of Fonger to include an antenna as taught by Purdy because there is no need to remotely communicate with or energize the detector of Fonger. As explained at Col. 4, lines 26-32 and 50-55, Fonger discloses a *temporary* cardiac output probe assembly for measuring and monitoring cardiac output during the post-operative recovery period following open heart surgery. Since the Fonger probe is specifically designed for in-hospital use when the patient is under the direct supervision of a physician, there is simply *no need* to modify Fonger to include an antenna for remote communication, as taught by Purdy. Moreover, modifying Fonger to communicate wirelessly may render the device less effective as a hard-wired device generally transmits a better signal. Such a modification is also not a simple substitution, as the detector of Fonger is not configured to work with an antenna. The modification would require that the sensor be entirely reconstructed or replaced to allow for use with an antenna. However, such a configuration would alter the structure of the detector, and thus may interfere with the specific configuration disclosed by Fonger – namely, a detector having tines that enable the detect to be embedded in tissue. Accordingly, claim 18, as well as claims 19-25 and 27 which depend therefrom, further distinguish over Fonger and Purdy, taken

alone or combined, and represent allowable subject matter.

Claims 12 and 14

Claims 12 and 14 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Fonger in view of Purdy, as applied to claims 1-11, 13, and 15-27, and further in view of U.S. Patent 5,104,398 to Quackenbush ("Quackenbush").

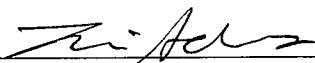
Claims 12 and 14 depend from claim 1, and therefore distinguish over Fonger and Purdy for the same reasons discussed above with respect to claim 1. Quackenbush is merely relied on by the Examiner to teach "the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and wherein the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter," as recited in claims 12 and 14. Accordingly, Quackenbush does not remedy the deficiencies of these references. Claims 12 and 14 therefore represent allowable subject matter.

Conclusion

In conclusion, Applicant submits that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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